



Monoclonal antibodies production in Wave and Stirred Tank bioreactors

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The rapid increase in the number of monoclonal antibodies (mAbs) which are being regularly approved for therapeutic use results in the need of their large scale production. However, this requires the development of bioreactors and processes simple to operate and easily scaled-up, that allow cultivation of mammalian cells. The Stirred Tank bioreactor is the traditional and most widely used reactor type, mainly due to the know-how acquired with microbial fermentation, its flexibility and suitability for different cell types, operation modes, products and working volumes.^[1] However, recently, disposable bioreactors, such as the new Wave reactor, are becoming increasingly popular due to their low initial and lifetime costs, simplified scale-up, reduced turn-around time between runs and low risk of cross-contamination.^[2]

Due to the current lack of comparative studies about these different technologies, we are optimizing and comparing mAb production in both Stirred Tank and Wave bioreactors. Different modes of operation are being tested (batch and fed-batch), and the use of microcarrier technology for culture of anchorage-dependent cells will also be assayed. Furthermore, it is important to evaluate the product in terms of biological activity, assuring that it maintains full functionality, by assessing how the glycosylation pattern is affected during the process of production in both reactors.

- [1] Ozturk SS, Hu W-S (eds.), "Cell Culture Technology for Pharmaceutical and Cell-Based Therapies", CRC Press, Taylor & Francis Group: New York, (2006).
- [2] Jain E, Kumar A, "Upstream processes in antibody production: Evaluation of critical parameters", *Biotechnol. Adv.* (2008) **26**:46-72.